

Remarks

The Office Action dated February 24, 2003 has been received and reviewed. Claims 1, 4 through 7, 11 through 15, 23 through 25 and 27 through 36 are pending in the application. All claims stand rejected. This application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Rejections Based on Xiang et al.

Claims 1, 4 through 7, 11 and 12 have been rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Xiang et al. (1994, *Molecular Cloning and Expression of Alternatively Spliced PITSLRE Protein Kinase Isoforms*, Journal of Biological Chemistry, Vol. 269, No. 22, pp. 15,786-15,794) ("Xiang"). Further, claims 13 through 15, 23 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Xiang. Applicants respectfully traverse the rejections as set forth herein.

Xiang discloses that multiple mRNAs may be transcribed from multiple duplicated genes and that, due to alternative splicing events, these transcripts may be translated into PITSLRE protein kinase isoforms ranging in size from 50 to 110 kDa. Most of the resulting isoforms contain the p58^{GTA} open reading frame (ORF) and p58^{GTA} activity appears to be involved.

Claims 1 and 5 through 7 have been cancelled herein rendering the rejection as to these claims moot.

Amended independent claim 4 recites a heterologous nucleic acid molecule comprising a recombinant nucleic acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:7, and combinations thereof. As recognized in the outstanding Office Action, "Xiang [] does not teach any function associated with the sequence corresponding to the fragments identified in the instant application as a G2/M cell cycle-dependent IRES". Accordingly, "it would not be obvious to excise those fragments from the nucleic acid taught by Xiang [] or insert those fragments into a heterologous nucleic acid." *Office Action*, page 3, ¶ 1. Therefore, as recognized by the Examiner, claims directed to the sequence set forth as SEQ ID NO:1 or 7 comprised within a heterologous nucleic acid would be patentable over Xiang. Similarly, it is respectfully submitted that a heterologous nucleic acid molecule having a recombinant nucleic acid sequence

set forth as SEQ ID NO:1, 7, or combinations thereof, comprised therein, as recited in amended independent claim 4, is also patentable over Xiang.

Claims 11, 12 and 14 have been amended herein to depend from newly added independent claim 37. Due to indirect dependencies, claims 13, 15, 23 and 24 now depend from new claim 37 as well. New claim 37 recites a recombinant nucleotide sequence comprising SEQ ID NOs:1, 4-6 or 7 comprised within a heterologous nucleic acid. The Examiner has recognized that such claim is patentable over Xiang. *See, Office Action*, page 3, ¶ 1. Accordingly, as claims 11 through 15, 23 and 24 depend from claim 37, these claims should be patentable over Xiang for at least the above-stated reasons and the rejections should be withdrawn.

Rejections Based on Gururajan et al.

Claims 25 and 27 through 36 have been rejected under 35 U.S.C. § 102(a) as assertedly being anticipated by Gururajan et al. (1998, *Duplication of a Genomic Region Containing the Cdc2L1-2 and MMP21-22 Genes on Human Chromosome 1p36.3 and their Linkage to D1Z2*, Genome Research, Vol. 8, No. 9, pp. 929-939) (“Gururajan”). Applicants traverse the rejection.

Gururajan discloses that the p36.3 region of human chromosome 1 consists of two identical genomic regions, each of which contain a Cdc2L gene linked to a metalloprotease (MMP) gene in a tail-to-tail configuration. It further discloses that the products of the Cdc2L genes encode PITSLRE kinases.

In contrast, amended claim 25 recites a heterologous nucleic acid molecule consisting essentially of a recombinant nucleic acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, and combinations thereof, the recombinant nucleic acid sequence initiating the translation of mRNA in a eukaryotic cell. As with Xiang, it is recognized in the outstanding Office Action that Gururajan “does not teach any function associated with the sequence corresponding to the fragments identified in the instant application as a G2/M cell cycle-dependent IRES”. Accordingly, “it would not be obvious to excise those fragments from the nucleic acid taught by Gururajan [] or insert those fragments into a heterologous nucleic acid molecule.” *Office Action*, page 4, ¶ 1. As such, it is respectfully submitted that a heterologous nucleic acid molecule consisting essentially of a recombinant nucleic acid sequence corresponding to the fragments identified in the instant application as a G2/M cell cycle-

dependent IRES, as recited in amended claim 25, would also not be obvious over Gururajan. Accordingly, claim 25 is patentable over Gururajan.

Each of claims 27 through 35 depend, either directly or indirectly, from amended independent claim 25. Thus, these claims are believed to be patentable over Gururajan for at least the previously stated reasons.

Claim 36 indirectly depends from newly added claim 37. As previously stated, new claim 37 recites a recombinant nucleotide sequence comprising SEQ ID NO:1, 4-6 or 7 comprised within a heterologous nucleic acid. As previously stated, the Examiner has recognized that such claim is patentable over Gururajan. *See, Office Action*, page 4, ¶ 1. Accordingly, claim 36 is patentable over Gururajan for at least the same reasons.

The rejection of each of claims 25 and 27 through 36 is believed to be overcome and applicants respectfully request withdrawal thereof.

35 U.S.C. § 112 Rejections

Claims 1, 6, 7, 11 through 15, 23 and 24 have been rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, it was thought that “a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acid molecules having the function of a G2/M cell cycle-dependent IRES.” *Office Action*, page 7, ¶ 1. Accordingly, it was thought that only those sequences explicitly set forth in the specification that have been demonstrated as a G2/M cell cycle-dependent IRES meet the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 1, 6 and 7 have been cancelled by way of the present amendment rendering the rejection of these claims moot.

Claims 11, 12 and 14 are amended to depend from newly added claim 37. Due to indirect dependencies, claims 13, 15, 23 and 24 now depend from new independent claim 37 as well. As stated previously, new claim 37 recites a recombinant nucleotide sequence comprising SEQ ID

NO:1, 4-6 or 7 comprised within a heterologous nucleic acid. As such, claim 37 relates to the sequences set forth in the specification and demonstrated as G2/M cell cycle-dependent IRES'. Accordingly, it is respectfully submitted that claim 37 meets the written description provisions of 35 U.S.C. § 112, first paragraph.

As claims 11 through 15, 23 and 24 depend, either directly or indirectly from claim 37, the 35 U.S.C. § 112, first paragraph, rejection of these claims is believed to be overcome and applicants respectfully request withdrawal thereof.

Claims 25 and 27 through 35 have been rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. More particularly, the Office Action states that the Markush group appears to include species that are not set forth in the claim and is, accordingly, indefinite because the identity of those species is not known. Claim 25 has been amended herein, as suggested by the Examiner, to recite a heterologous nucleic acid molecule consisting essentially of a recombinant nucleic acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, and combinations thereof, the nucleic acid sequence initiating the translation of mRNA in a eukaryotic cell. The rejection of claim 25 should thus be overcome. As claims 27 through 35 depend, either directly or indirectly from claim 25, the rejection as to these claims is believed to be overcome as well.

New claims

Claims 37 through 40 have been added by way of the present amendment. It is respectfully submitted that each of these claims is adequately supported by the as-filed specification and adds no new matter to the instant application. Newly added independent claim 37 is believed to be patentable over the art of record for the reasons previously set forth. Each of claims 38 and 39 depend from newly added claim 37 and are, thus, believed to be patentable over the art of record for at least the above-stated reasons.

Newly added claim 40 depends from amended independent claim 4. Claim 4 is believed to be patentable over the art of record for the reasons previously set forth and, thus, claim 40 is believed to be patentable over the art of record for at least the above-stated reasons.

Conclusion

In view of the amendments and remarks herein, the claims are believed to be in condition for allowance and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is invited to contact applicants' attorney at the address or telephone number given herein.



Respectfully submitted,

A handwritten signature in black ink, appearing to read "Allen C. Turner".

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